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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,025

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Richard W. LeVaughn

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GARDNER GROFF GREENWALD & VILLANUEVA. PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,025	Applicant(s) LEVAUGHN ET AL.	
	Examiner MICHAEL G. MENDOZA	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites opening and preventing a housing. It is unclear as to how the housing opens. The claim does not recite what any structural limitations that enable the housing to open.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 7-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schraga 6228100.
6. As to claims 1-3, Schraga teaches a device for sampling a body fluid, the device comprising a housing and a lancet cartridge (fig. 4), a drive mechanism (fig. 2), the drive mechanism comprising a contact face 26; wherein the contact face of the drive mechanism comprises an angled female recess 26, and the lancet cartridge has at least one complementary angled male profile 76; wherein the housing comprises a resilient

portion having a protuberance thereon for engaging at least one recess in the lancet cartridge (fig. 5).

7. As to claims 7-9, Schraga teaches a device for sampling a body fluid, the device comprising a housing and a plurality of lancets, the plurality of lancets 70 being interconnected by a flexible web (fig. 4); and a plurality of alignment tabs 76, each alignment tab associated with a respective one of the plurality of lancets 70, wherein the housing comprises a channel 26 in which the alignment tabs are received (fig. 4); and wherein the plurality of lancets are arranged in a generally circular array, and wherein the channel comprises a ring-shaped channel portion (as seen in fig. 2, the cartridge has a channel portion that 60 goes through) and an extension channel portion 52 extending radially from the ring-shaped channel portion.

8. As to claims 10 and 11, Schraga teaches a device for sampling a body fluid, the device comprising: a housing (fig. 4) having an arm with a wedge-shaped profile (fig. 6); at least one lancet 70, each lancet having a body portion 75, a sharp tip 74, and an endcap 72; an advancing mechanism (fig. 5) for advancing the at least one lancet into contact with the arm of the housing to drive the wedge-shaped profile between the body portion of the lancet and the endcap, and thereby separate from the body portion of the lancet (col. 4, lines 1-13); and wherein the arm further comprises a ramp (fig. 6).

9. As to claims 12-19, Schraga teaches a lancet cassette for removable installation within a sampling device, the lancet cassette comprising a plurality of lancet and a flexible web interconnection the plurality of lancets (fig. 4); wherein the plurality of lancets are arranged in a circular array with sharp lancet tips thereof oriented radially

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outwardly (fig. 4); a plurality of alignment tabs 76, each alignment tab attached to an inner end of a respective one of the plurality of lancets (fig. 4); wherein the plurality of lancets are positioned on an annular carrier disk having a central opening (as seen in fig. 2, the cartridge has a channel portion that 60 goes through); further comprising at least one hook 72 (hooks 92) for engagement with anti-tamper shelf portion(92 functions a shelf and one can tell if the lancet has been tampered with because the hook will be removed); wherein each lancet comprises a removable protective endcap 72, and wherein the lancet further comprises a well 92 for receiving and retaining the endcap out of a path of travel; a lower face having surface features for engaging an advancing mechanism (fig. 5); and further comprising an outer circumferential rim having a plurality of detents 76..

10. As to claim 20, Schraga teaches a device for sampling a body fluid, the device comprising: an outer housing having first and second portion hingedly connected (fig. 4), an opening 54, and an arm having a wedge-shaped profiled (fig. 6); a lancet cassette, the lancet cassette comprising a plurality of lancets arranged in a circular array (fig. 4), and a flexible web interconnecting the plurality of lancets (fig. 4), each lancet comprising a lancet body 75, a sharp tip 74, and a protective endcap 72, a drive mechanism (fig. 2); and an advancing mechanism (fig. 5) for advancing the at least one lancet into contact with the arm of the housing to drive the wedge-shaped profile between the body portion of the lancet and the endcap, and thereby separate from the body portion of the lancet (col. 4, lines 1-13); and wherein the arm further comprises a ramp (fig. 6).

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11. Claims 1, 7, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Munsch et al. 4794926.

12. As to claim 1, Munsch et al. teaches a device for sampling a body fluid, the device comprising a housing (11 + 25) and a lancet cartridge (fig. 3); a drive mechanism (fig. 10), the drive mechanism comprising a contact face (tip of 42).

13. As to claim 7, Munsch et al. teaches a device for sampling a body fluid, the device comprising a housing (11 + 25) and a plurality of lancets (fig. 3), the plurality of lancets being interconnected by a flexible web (fig. 3).

14. As to claims 12 and 13, Munsch et al. teaches a lancet cassette for removable installation within a sampling device, the lancet cassette comprising a plurality of lancet and a flexible web interconnection the plurality of lancets (fig. 3); wherein the plurality of lancets are arranged in a circular array with sharp lancet tips thereof oriented radially outwardly (fig. 3).

15. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. 4990154.

16. Brown et al. teaches a device for sampling a body fluid, the device comprising a housing 14 having an opening 38, a lancet 54, a drive mechanism 20, a lancing path, a dampening fin 22, and a pair of flanges 42 having inwardly inclined faces.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga in view of Brown et al. 4990154.

19. Schraga teaches the sampling device of claim 20. It should be noted that Schraga fails to teach a dampening fin adjacent an opening.

20. Brown et al. teaches a device with a common fin 22 to spring back the lancet. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the fin 22 of Brown et al. in the device of Schraga to to push the lancet back after activation and cause less pain for the person being lanced (col. 6, lines 54-57)

21. Schraga/Brown teaches the sampling device of claim 20, further comprising a guide channel defined between a pair of flanges 42 positioned on opposite sides of the opening (see figs 2, 3, & 5).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731